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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,478	06/07/1999	PHILIP E BRANTON	50013/002003	8679

7590 03/05/2002  
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EXAMINER

CHEN, SHIN LIN

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.  
09/214,478

Applicant(s)

Branton et al.

Examiner

Shin-Lin Chen

Art Unit

1633



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Feb 4, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Feb 4, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: Claims 81 and 84, 88 and 89, and 95 and 96 are duplicate claims, respectively.

4. ☒ Applicant's reply <sup>could</sup> ~~has~~ overcome the following rejection(s):  
112 first paragraph written description rejection and 103(a) rejection if the amendment filed 2-4-02 is entered
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Applicants argue that the specification teaches the preparation of expression vector and methods for their use for expressing genes in cell in vivo, and the data of increasing apoptosis in vitro can be applied to increase apoptosis in
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: None  
Claim(s) objected to: None  
Claim(s) rejected: 81-100
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Continued from Advisory Action:

*in vivo*. Applicants further argue that declaration of Dr. Philip Branton shows induction of apoptosis *in vivo* via administration of adenoviral vector expressing E4orf4 (amendment, p. 6, 7). This is not found persuasive because the administration route shown by Dr. Philip Branton is intratumoral injection and no other administration route of the adenoviral vector expressing E4orf4 has been shown. As discussed in the preceding Official action mailed 10-3-01 (Paper No. 16), the fate of the DNA vector itself, the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced are all important factors for a successful gene transfer *in vivo*. Absent evidence of inducing apoptosis via administration route other than intratumoral injection, one skilled in the art at the time of the invention would require undue experimentation to practice over the full scope of the invention claimed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

*Scott D. Priebe*  
SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER